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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/122,144 07/24/98 BLUMBERG R B0801/7117

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HM12/0801

EXAMINER

EWOLDT, G

ART UNIT

PAPER NUMBER

1644

16

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

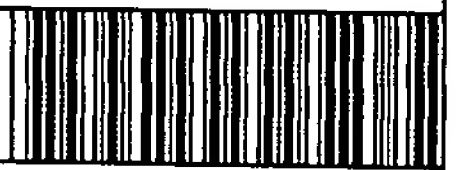
Office Action Summary

Application No.
09/122,144

Applicant(s)
Blumberg et al.

Examiner
Gerald Ewoldt

Group Art Unit
1644



☒ Responsive to communication(s) filed on May 30, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 25-60 is/are pending in the application.

Of the above, claim(s) 35-60 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 25-34 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 447

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. This application claims priority to U.S. Application Serial Nos. 08/899,856 (now U.S. Patent No. 6,030,613), 08/578,171, and 08/374,159 (now U.S. Patent No. 6,086,875). The specification must be amended accordingly.
2. Claims 25-60 are pending.
3. Applicant's election of Group II, claims 10-17, in Paper No. 12, is acknowledged. Applicant's further election of the antigen species "hepadnaviridae" and FcRn binding partner species "Fc fragment of IgG" are acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
4. Applicant has elected Group II, claims 10-17, drawn to a pharmaceutical preparation for activating an immune response against a tumor antigen comprising an antigen and a pharmaceutically acceptable carrier. However, because of Applicant's cancellation of pending claims 1-24 and addition of claims 25-60, and Applicant's election of the antigen species hepadnaviridae (a virus), antigens related to a tumor antigen will be considered a non-elected embodiment. Additionally, Applicant's new claims 35-44, drawn to a pharmaceutical preparation comprising an autoimmune disease antigen, and new claims 45-60, drawn to a pharmaceutical preparation comprising a cytokine, would be restricted into different Groups as being drawn to different products. Therefore, Claims 35-60 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 25-34, read on the elected species and are being acted upon, wherein the pharmaceutical preparation that is being acted upon is a pharmaceutical preparation wherein the antigen that is characteristic of a pathogen is hepadnaviridae and the FcRn binding partner is an Fc fragment of IgG.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 25-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) In claims 25-28, the recitation of the term "FcRn" renders the claims ambiguous and indefinite because the full name should be recited in the claim.

B) In claim 25, line 4 it is not clear what is meant by the phrase, "antigen that is characteristic of a pathogen".

C) In claim 26, the recitation of the terms "non-specific IgG" and "FcRn binding fragment of IgG" render the claim ambiguous and indefinite because the terms have not been defined in the specification.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 25-31 and 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 92/05793.

WO 92/05793 teaches a pharmaceutical preparation for activating an immune response comprising a conjugate of a hepadnaviridae (hepatitis) (see claims 8-9) antigen, an Fc binding fragment of IgG, and a pharmaceutically acceptable carrier including saline (see particularly page 3, paragraphs 1-2, page 7, paragraph 4, and page 9, line 5). "An antibody, or fragment thereof, specific for an Fc receptor (page 7, lines 29-30) and "an antibody, or fragment thereof, specific for an Fc receptor for immunoglobulin G" (claim 11), would define both an Fab fragment specific for IgG and any IgG Fc fragment as claimed in claim 27. The human homolog of the FcRn is used to immunize humans by taking advantage of the well known inherent property of the receptor that it passes all IgG nonspecifically (page 7, lines 25-26) through the mucosal epithelial barriers on which it is found. Therefore it is an inherent property of any IgG Fc fragment that said fragment would constitute an FcRn binding partner as claimed. The reference composition is considered the same as that recited in the claims irrespective of the intended route of administration. Additionally, claim 34 is included because absent a claim of sterility, the pharmaceutical preparation would necessarily be nonaseptic.

The reference clearly anticipates the claimed invention.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 25-34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 92/05793 in view of U.S. Patent No. 5,428,130 and/or the well known facts disclosed in the specification on page 7, lines 2-3.

WO 92/05793 has been discussed supra.

WO 92/05793 differs from the claimed invention in that it does not teach a pharmaceutical preparation in an oral formulation including a solid or an elixir or syrup, in an aerosol formulation comprising a propellant, in a nasal formulation, or in a nonaseptic formulation.

The '130 patent teaches a pharmaceutical preparation comprising an antigen conjugated to an Fc fragment of IgG (see particularly column 10, lines 19-49, and column 11, line 1), said pharmaceutical preparation further comprising an oral formulation including a solid and liquid (elixir), or an aerosol formulation for inhalation (see particularly column 31 paragraph 2). The reference further teaches that said pharmaceutical preparation is particularly useful for the treatment of individuals in need of antiviral therapy (see particularly column 6, paragraph 2).

The specification discloses the well known fact that the FcRn is present in epithelial tissue of human children and adults (page 7, lines 2-3).

From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute an Fc fragment of IgG, as taught by the '130 patent, as the FcRn binding partner in a conjugate of a hepadnaviridae antigen, an FcRn binding partner, and a pharmaceutically acceptable carrier, as taught by WO 92/05793, said pharmaceutical preparation further comprising an oral formulation including a solid and liquid (elixir), or an aerosol formulation for inhalation, also taught by the '130 patent, given the well known fact that the FcRn is found on epithelial tissue, as disclosed by the specification. One of ordinary skill in the art would have been motivated to prepare said pharmaceutical preparation for the treatment of individuals in need of antiviral therapy, as taught by the '130 patent using an Fc fragment of IgG as the FcRn binding partner because the Fc fragment can be obtained more easily and in larger quantity than FcRn specific Fab fragments. Further, one of ordinary skill in the art would have been motivated to prepare said preparation in an oral formulation including a solid and liquid (elixir), or an aerosol formulation for inhalation, because preparations administered through said routes are cheaper, safer, and easier to administer. Claim 32 is included in the rejection because the use of a propellant for the delivery of an aerosol formulation is well within the purview of one of ordinary skill in the art at the time the rejection was made and adds no patentable weight to the invention. Claim 34 is included because absent a claim of sterility, the pharmaceutical preparation would necessarily be nonaseptic.

11. Claims 25-34 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 08/578,171 which has a common assignee with the instant application.

Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future patenting of the copending application. The '171 application discloses a composition comprising a hepadnaviridae

antigen conjugated to an FcRn binding partner comprising an Fc fragment of IgG, said composition further comprising an oral formulation including a solid and an elixir or syrup, or an aerosol formulation for inhalation further comprising a propellant, and a nasal formulation, said composition being nonaseptic (see particularly page 15 last paragraph - page 16). While the '171 application teaches a "composition" and the instant application recites a "pharmaceutical preparation", it would be an inherent property of a composition intended for use in the treatment of a patient that said composition would necessarily comprise a "pharmaceutical preparation".

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-23 of copending Application No. 09/578,171. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the same reasons set forth above in the provisional 103(a) rejection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 25-34 are directed to an invention not patentably distinct from claims 21-23 of commonly assigned 08/578,171 for the same reasons set forth above under the obviousness type double patenting rejection.

Commonly assigned 08/578,171, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the

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commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78© and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

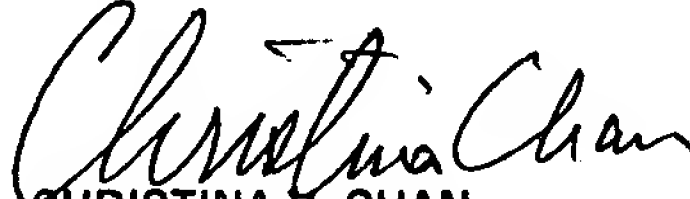
A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g).

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Tech Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Examiner
Group 1640
July 28, 2000


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